ARC 9180B

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 13, "Sterile Compounding Practices," Iowa Administrative Code.

The amendments clarify the definition of "beyond-use date" for a sterile compounded product to mean the date following compounding after which a product may not be stored, administered, or transported. The amendments also clarify the approved storage periods for high-risk compounded preparations based on the temperature of the preparation during storage.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the June 30, 2010, Iowa Administrative Bulletin as **ARC 8913B**. The Board received written comments regarding the proposed amendments from one pharmacist. The adopted amendments differ from those published under Notice. Item 1 is changed to clarify that administration of a sterile compound shall not begin after the beyond-use date.

The amendments were approved during the September 28, 2010, meeting of the Board of Pharmacy.

These amendments will become effective on December 8, 2010.

These amendments are intended to implement Iowa Code sections 126.10, 155A.2, 155A.13, and 155A.28.

The following amendments are adopted.

ITEM 1. Amend rule **657—13.2(124,126,155A)**, definition of "Beyond-use date," as follows:

"Beyond-use date" means the date or time following compounding after which the preparation shall not be stored or transported and after which administration of the preparation shall not begin. The beyond-use date is determined from the date or time compounding of the preparation is completed.

ITEM 2. Amend paragraph **13.13(1)"e"** as follows:

e. For a sterilized high-risk preparation, in the absence of the preparation's passing a sterility test, the storage ~~periods~~ period beyond-use date shall not exceed the following:

(1) At controlled room temperature, ~~for~~ 24 hours;

(2) At a cold temperature, ~~for~~ 3 days; or

(3) In a solid-frozen state between minus 25 and minus 10 degrees Celsius, ~~for~~ 45 days.

[Filed 10/14/10, effective 12/8/10]

[Published 11/3/10]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 11/3/10.